

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/126,096 07/30/98 THORSETT

E 002010-137

021839 HM22/0604
BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA VA 22313-1404

EXAMINER

RAO.D

ART UNIT

PAPER NUMBER

1624

DATE MAILED:

06/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/126,096

Applicant(s)
Thorsett et al.

Examiner
Deepak Rao

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Mar 26, 2001

2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-4, 7, 10, 12, 13, and 15-22 are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-4, 7, 10, 12, 13, and 15-22 are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s) _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 15 & 17

20) ☐ Other:

Art Unit: 1624

DETAILED ACTION

This office action is in response to applicant's response filed on March 28, 2001.

Claims 1-4, 7, 10, 12-13 and 15-22 are pending in this application.

The following rejections are withdrawn:

The improper Markush rejection of the previous office action is hereby withdrawn in view of applicant's amendments which limit the claims to the elected invention.

The rejection under 35 U.S.C. 112, first paragraph of the previous office action is withdrawn in view of applicant's arguments and remarks.

The rejection under 35 U.S.C. 112, second paragraph of the previous office action is withdrawn, all except for the claim(s)/reasons provided here below.

The rejection under 35 U.S.C. 103(a) over JP 4,154,732 of the previous office action is withdrawn in view of applicant's arguments.

The following rejections are maintained:

1. Claims 16 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- (A) In claim 16, the last line there is a term R^6 which is not found to be present anywhere in the structural formula. The claim was rejected in the previous office

Art Unit: 1624

action for having no definition for the above term. Applicants amended the claim to include a structural formula without that term, however, the amendment inserted this term in the last line of the claim, which is not understood. Replacing with R⁶ is suggested.

- (B) Regarding claim 18, the phrase "such as" (see line 6) renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). This was indicated in the previous office action (see page 8, reason # 9) and applicants responded that the referenced phrases are deleted. The claim still contains the above referred phrase. Deletion of "such as that" from line 6 appears to put the claim in acceptable language and such correction is suggested.

2. Claims 1-4, 7, 10, 12-13 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al., WO 96/22966. The reference teaches a generic group of compounds of formula (I) which is identified in applicant's response page 15. The instant claims differ by having a non hydrogen substituent R⁴ in place of a hydrogen in the reference. As indicated in the previous office action, the instant compounds are homologs of the reference compounds, i.e., they differ by having a methyl substituent (R⁴) as compared to hydrogen in the reference. Applicant argues that the reference teaches away from the present invention because the most preferred compounds of the reference contain a Y group that is equal to C(O). however.

Art Unit: 1624

the reference clearly teaches Y definition to contain SO₂ also. Where the specific compound falls within the ambit of a "very limited number of compounds", the fact that a specific embodiment is taught to be preferred is not controlling, since all disclosures of the prior art, including unpreferred embodiments, must be considered." *In re Lamberti*, 545 F.2d 747,750, 192 USPQ 278, 280 (CCPA 1976). "The question under 35 U.S.C. 103 is not merely what the reference expressly teaches but what it would have suggested to one of ordinary skill in the art at the time the invention was made." As can be evidenced from the teachings of the reference, the instant compounds differ by having a methyl group in place of hydrogen. H vs. Me is not deemed patentably distinct absent evidence of superior or unexpected properties. See *In re Wood*, 199 USPQ 137; *In re Lohr*, 137 USPQ 548 regarding the addition of a methyl group to a known compound. Further, the reference compounds are disclosed to have the same therapeutic use as the instant compounds. Therefore, it is maintained that the instantly claimed compounds would have been obvious to one having ordinary skill in the art.

Newly presented claims 19-22 are also rejected under 35 U.S.C. 103(a) over Adams et al., WO 96/22966 for the reasons provided.

3. Claims 1-4, 7, 10, 12-13 and 15-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 (and other dependent claims) of copending application 09/126,095 for the reasons of record and further, in view of the reasons provided above. Applicant's disagreement is acknowledged.

Art Unit: 1624

Information Disclosure Statement

Receipt is acknowledged of the Information Disclosure Statements filed on April 13 and May 16, 2001 and copies are enclosed herewith. Further, copy of IDS filed on March 30, 1999 (page 2 or 3) is enclosed herewith, duly acknowledging the references that were crossed off previously. The contents of US Provisional Applications cited on page 1 of the IDS (filed March 30, 1999) are considered, but crossed off from the statement because they have not been listed as published documents and therefore, will not appear on a patent issuing from instant application. The following reasons apply: (i) they do not have a publication date (publication date column is left blank in the IDS) as required by 37 CFR 1.98(b) and (ii) there may be non provisional applications that correspond to these provisional applications pending in the office and all pending U.S. Applications are preserved in confidence, see MPEP § 2127, paragraph IV.

Conclusion


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

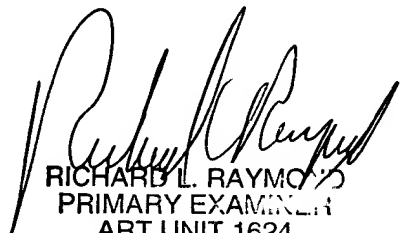
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 1624

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (703) 305-1879. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Deepak Rao 
June 1, 2001


RICHARD L. RAYMOND
PRIMARY EXAMINER
ART UNIT 1624